JUL 2 3 2002

510(k) Summary

K022171

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Scott Thiel
Date Prepared: July 2, 2002

2) Device name

Proprietary name: Accu-Chek Compact System
Classification name: Glucose Dehydrogenase, Glucose
(21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

We claim substantial equivalence to the current legally marketed Accu-Chek Compact System (K004010).

4) Device Description

Instrument Operating Principle -- photometry
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale.

The Accu-Chek Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

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510(k) Summary, Continued

6) Similarities The proposed modification is relatively modest in scope. All of the following are claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in whole blood. The test device is indicated for professional use and over-the-counter sale. This device is not suitable for testing neonate samples.
Test principle	Glucose dehydrogenase chemical reaction. The instrument measures the extent of color change (photometric) caused by the presence of glucose in the sample. The amount of color change is related to the glucose concentration in the blood sample.
Monitor coding procedure	The code is automatically read from the test drum upon insertion of the test drum into the meter.
Test strip storage conditions	Store at room temperature between +36° F(+2° C) and +86° F(+30° C).
Test strip operating conditions	Between +50° F(+10° C) and +104° F(+40° C).
Quality control acceptable range	The mean is strip lot specific and will be determined individually. The range of the controls is within ± 15 mg/dL or ± 15% compared to the determined mean.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.
Acceptable sample types	Capillary and venous whole blood samples

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510(k) Summary, Continued

Similarities, Contd.

Reportable range	10-600 mg/dL
Hematocrit range	25 – 65%
Warnings and precautions	For *in vitro* diagnostic use only.
Reagent active ingredients	• Glucose-dye-oxidoreductase* • Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium chloride • 2,18-Phosphomolybdic acid *(*from A. Calcoaceticus, recombinant from E. Coli*)
Minimum sample volume	3.5 µL
Under-dosed test strip detection method	Yes
Dosing test strips outside of meter	No
Meter physicial dimensions	4" L x 2" W x 1 1/2" H
Batteries required	Two 1.5 volt AAA alkaline batteries
Data transmission to external devices	Yes

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510(k) Summary, Continued

Difference

Feature	Accu-Chek Compact System (modified)	Accu-Chek Compact System (predicate)
Self-testing capillary whole blood sample collection sites	Finger, forearm, calf, thigh, upper arm, and palm	Finger

Performance Characteristics

The results of a study conducted at our manufacturing facility demonstrated consistent quality performance of this product. This study demonstrated good correlation ($r > 0.90$) between AST results and finger results under steady state conditions. With these data it is proved that the system accuracy with AST blood from calf, thigh and upper arm is unchanged from forearm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 3 2002

Mr. Scott Thiel
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k022171
Trade/Device Name: Accu-Chek Compact Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; LFR
Dated: July 2, 2002
Received: July 3, 2002

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K022171
Device Name: Accu-Chek Compact Test System

Indications for Use:

The Accu-Chek Compact system is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale.

The Accu-Chek Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022171